Department of Defense Individual's Briefing

ANTHRAX VACCINE

18 Aug 09

Briefing Outline

- Key Messages
- Policy, Threat and Disease
- Vaccine Facts and Safety
- Exemptions and Pregnancy
- Adverse Event Reporting

Key Messages

- Your health and safety is our # 1 concern
- Receiving the vaccination is the only round-the-clock protection available to protect service members against this very real threat
- The Food and Drug Administration say the anthrax vaccine protects against all forms of anthrax disease and is safe
- Vaccination protects you, your unit, and your mission

Policy History of the AVIP

- Dec 97: Secretary of Defense ordered the AVIP
- Mar 98: Vaccinations began in Southwest Asia
- Aug 98: Vaccinations began in Korea
- 2000-01: Slowdowns due to shortage. After supply restored, program resumed in 2002
- Oct 04: Injunction issued against DoD
- Jan 05: FDA issues Emergency Use Authorization (EUA)
- Dec 05: FDA formally issues Final Rule/Final Order
- Oct 06: Deputy Secretary of Defense issued AVIP policy to re-establish a mandatory program for those in higher risk areas and with special roles; policy allows voluntary vaccinations for other groups
- Dec 06: Under Secretary of Defense for Personnel and Readiness released DoD implementation guidance for the AVIP policy
- Dec 08: Vaccine route and dosing schedule change

Current Policy Implementation

Mandatory and Voluntary Vaccinations

- Vaccinations are mandatory for DoD service members, emergency essential designated civilians, and contractor personnel performing mission-essential services assigned to:
  - Central Command area of responsibility, the Korean Peninsula, and the Horn of Africa for 15 or more consecutive days
  - Special units with biowarfare or bioterrorism related missions
  - Specialty units with approved exception to policy
- Vaccinations shall begin, to the extent feasible, up to 120 days prior to deployment or arrival in higher threat areas

Current Policy Implementation

- Vaccinations are voluntary for DoD service members who are not in the mandatory groups and have received at least one dose of Anthrax Vaccine Adsorbed during or after 1998

- Vaccinations are voluntary for DoD civilians and adult family members; contractors and their accompanying US citizen family members:
  - Residing in Central Command area of responsibility, the Korean Peninsula, and the Horn of Africa for 15 or more consecutive days

- DoD Civilian Personnel Management Service concluded notification to national unions on 12 Jan 07

Threat

- Inhalation anthrax is 99% lethal if unprotected, unvaccinated, or untreated
- Anthrax spores are the most likely bioweapon
  - Relatively easy and cheap to produce
  - Extremely stable – can withstand harsh environmental conditions and remain dormant up to 50 years
  - Can be aerosolized and delivered in a variety of methods
  - Odorless, colorless, tasteless, difficult to detect

Anthrax Infections

- Recognized as an illness for centuries
- Once common where livestock were raised, now controlled using vaccine for livestock
- Human infection from direct contact with infected animals, animal products, or anthrax spores
- Still a problem in Asia and Africa
- Terror attacks via US mail in Fall 2001

Pathogenesis

- Spore enters through broken skin, gastrointestinal tract, or the lungs
- Collected by white blood cells
- Transported to nearest lymph nodes
- Bacteria multiply in lymph nodes
- Produce deadly toxins
- Toxins cause swelling, bleeding and death of the tissue and organs (lungs, brain, GI tract)

Infections

- Three types of Anthrax infection
  - Cutaneous Anthrax (Skin)
  - Gastrointestinal Anthrax (GI tract)
  - Inhalational Anthrax (lungs)

Cutaneous Anthrax

- Cutaneous: Contact with spore-infected animal hides or products through a break in the skin
- Incubation period: 1-5 days
- Symptoms: Papule forms in 1-2 days; changes to vesicle; ruptures to form ulcer and develops black eschar (scab); lasts 2-3 weeks

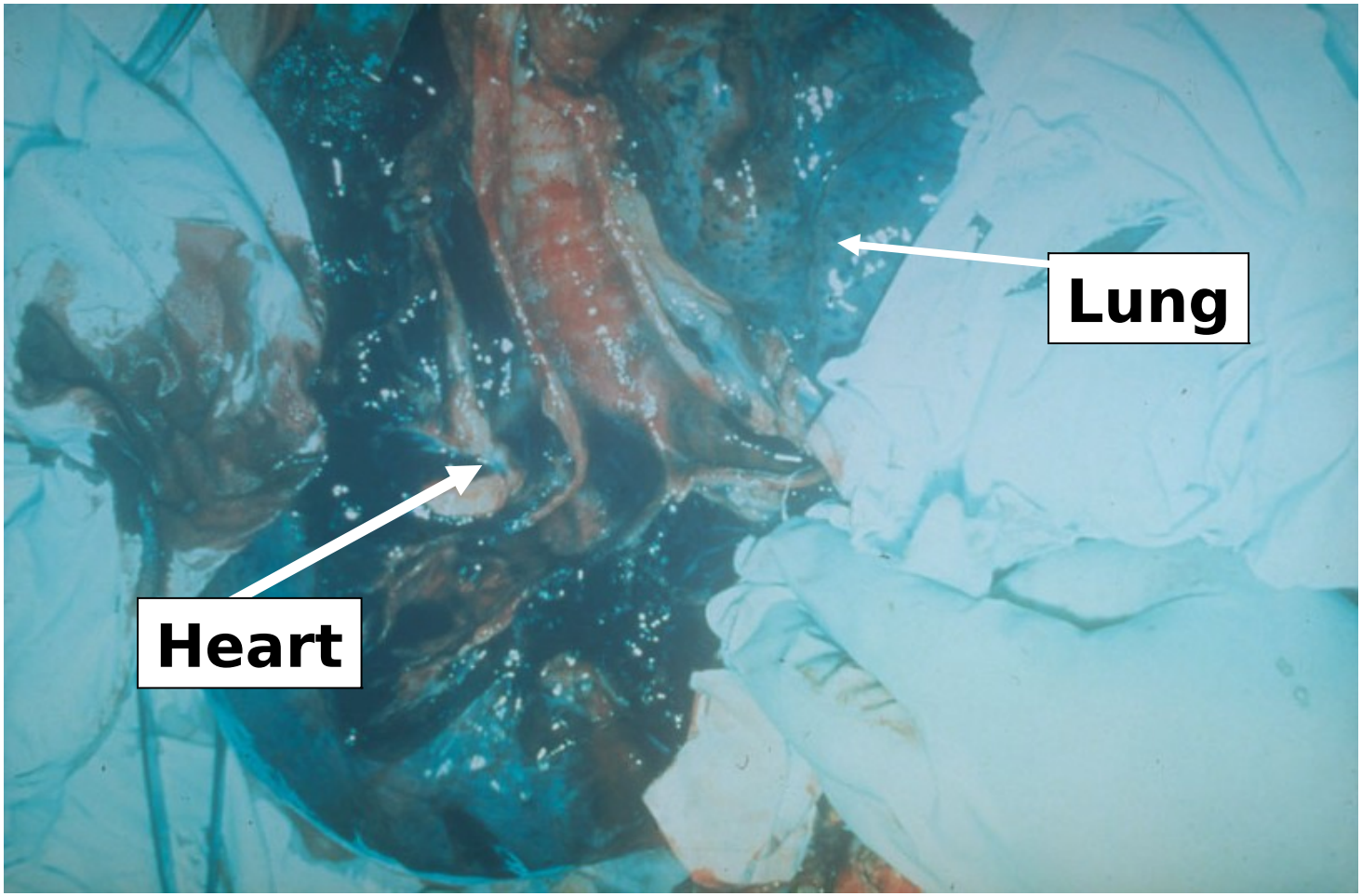
Gastrointestinal Anthrax

- Gastrointestinal: Ingesting poorly- or undercooked infected meat
- Incubation period: 2-5 days
- Symptoms: Fever, abdominal pain, nausea, vomiting of blood, and bloody diarrhea
- Mortality up to 50% due to late diagnosis, GI hemorrhage, massive fluid retention
- Oropharyngeal anthrax -> compromised airway

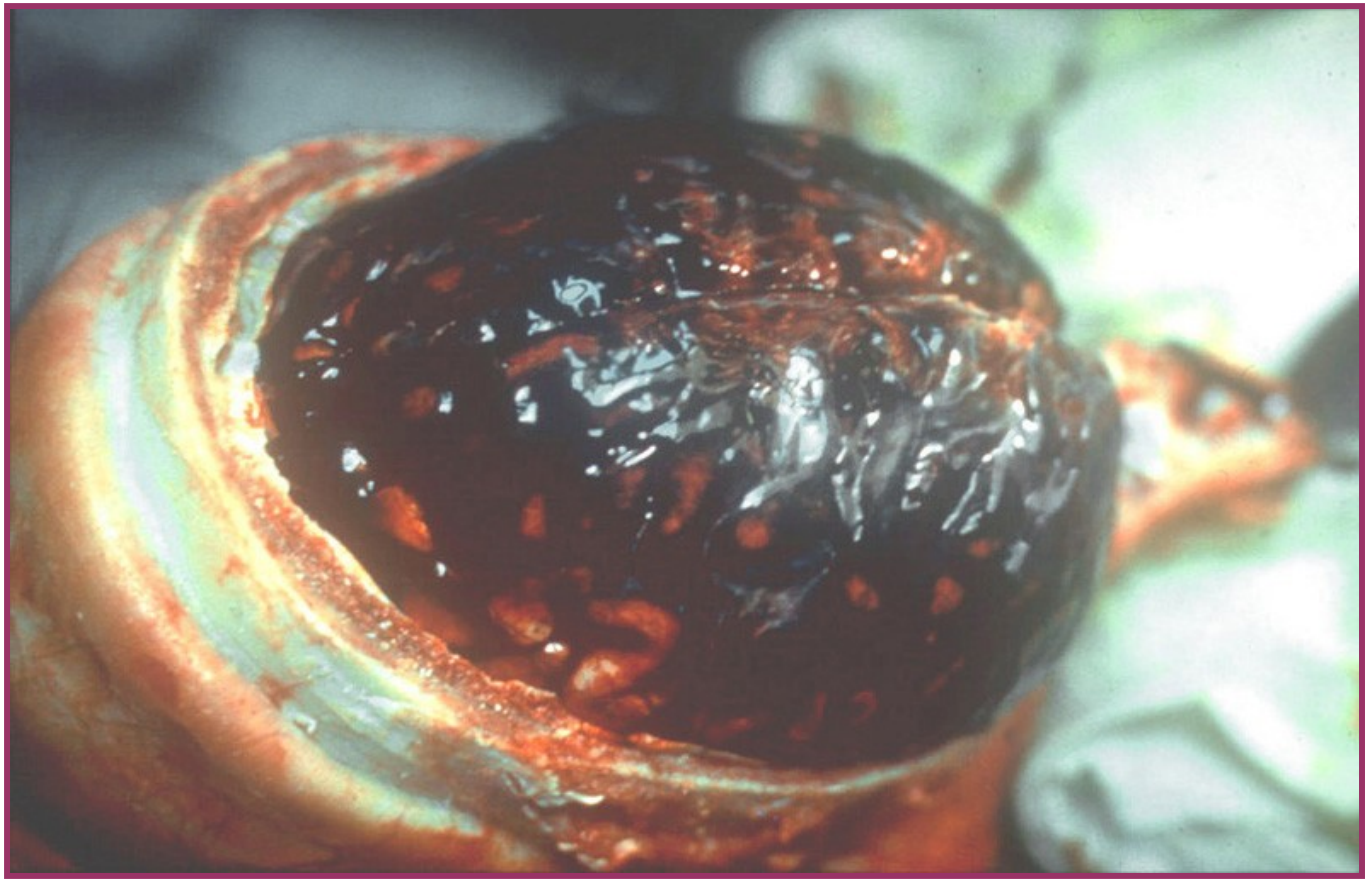
Inhalation Anthrax

- Inhalation: Spores enter lungs, collected by white blood cells, travel to lymph nodes. Spores rapidly multiply and produce toxins
- Incubation period: 1-6 days
- Symptoms:
  - Initially flu-like: Mild fever, myalgias and malaise, cough, chest discomfort, 2-4 days
  - Slight improvement, hours to days
  - Severe respiratory distress quickly progresses to shock and death in hours to days
- Toxins cause destruction of pulmonary and thoracic tissues, result in multiple organ failure

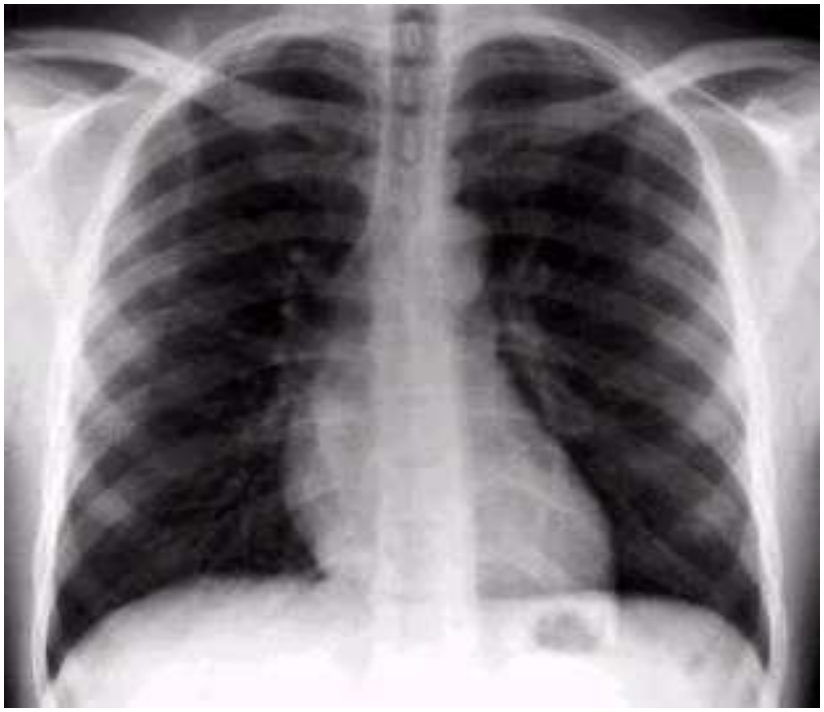
Chest Autopsy of Lethal Case of Inhalation Anthrax



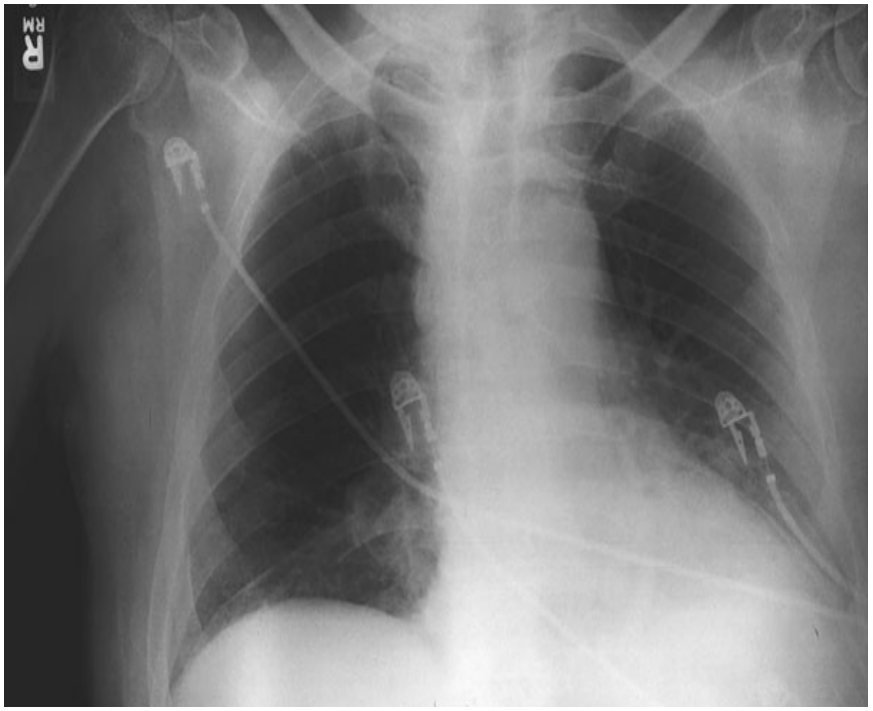
Brain Autopsy of Lethal Case of Inhalation Anthrax



Chest X-Ray in Anthrax



Normal Chest X-ray



Chest X-ray of Inhalation Anthrax Victim

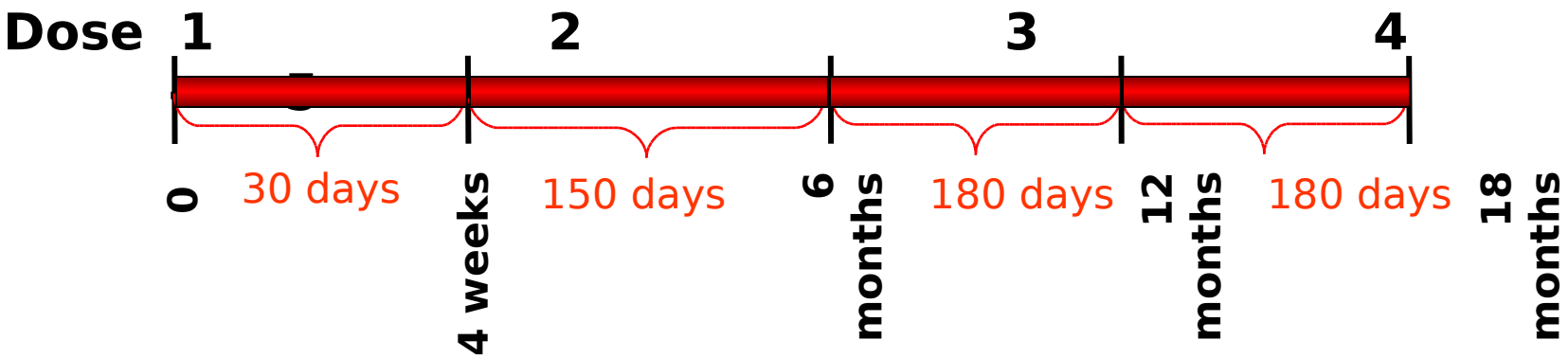
Anthrax Vaccine Facts

- Licensed by the Federal government since 1970
  - Administered in US to at-risk veterinarians, laboratory workers, and livestock handlers
  - Over 8.9 million doses to more than 2.2 million people since Mar 98
- Vaccine primes immune system to fight anthrax
- Manufactured in US by Emergent BioSolutions
  - "AVA," *BioThrax*™. Package insert with each vial.
  - Official name: Anthrax Vaccine Adsorbed

This vaccine contains no whole or live anthrax bacteria;
therefore, it is impossible to contract the disease from it.

Immunization Schedule

- 5 doses over 18 months, then annual booster
- Do not compress schedule
- Adjust schedule for individual delays
- Do not “restart” series if it has been interrupted



Injection Site Reactions

Many may experience temporary pain and swelling after the shot

Mild side effects such as redness and tenderness at the site of vaccination are co

- For both genders, IM administration significantly reduces adverse events at injection sites
- Monitoring of all adverse events
  - Burning
  - Soreness
  - Redness
  - Itching
  - Swelling
  - Local pain at the injection site

Exemptions from Vaccination

TEMPORARY PERMANENT

- Some people should not get anthrax vaccine
- Temporary medical exemptions include
  - Women who are pregnant, or uncertain if pregnant
  - Short-term immune suppression
  - Acute diseases, surgery
  - Medical evaluation or condition pending
- Permanent exemptions can include
  - Severe allergic reaction or other serious reaction after a previous dose of anthrax vaccine
  - People with a history of severe latex sensitivity
  - HIV infection or other chronic immune deficiencies
  - People who had Guillain-Barré Syndrome (GBS)
  - Recovery from previous anthrax infection

Anthrax vaccine is licensed for individuals from 18 to 65 years of age

Pregnancy

According to the CDC's Advisory Committee on Immunization Practices (ACIP):

"there is no convincing evidence of risk from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids."

- Vaccinations routinely deferred during pregnancy
- Before vaccination, ask each woman if she is pregnant or if there is the possibility of trying to become pregnant
- No reason to delay conception after vaccination
  - Anthrax-vaccinated & -unvaccinated women at Fort Stewart (*JAMA*, 2002): same rates of conception, delivery
  - Anthrax-vaccinated & -unvaccinated men at fertility clinic: same sperm concentration, rate of pregnancy
- Vaccination during pregnancy
  - Do not vaccinate pregnant women unless potential benefits of vaccination outweigh potential risk to fetus

Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
  - FDA and CDC review 100% of adverse-event reports
  - All VAERS forms reviewed by independent panel of expert civilian physicians for 4 years
- DoD requires healthcare workers submit a VAERS Form for
  - Loss of duty 24 hours or longer ($\geq$ 1 duty day)
  - Hospitalization
  - Suspected vaccine vial contamination
- Other submissions are encouraged
- Anyone can submit a VAERS Form

When in doubt, report it!

1-800-822-7967

www.vaers.hhs.gov

Reserve Component Adverse Event Guidance

- If someone experiences an adverse event in a non-duty status that is possibly associated with a vaccination
  - Should seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
  - Should Report the event to your unit Commander or designated representative as soon as possible
  - Should see local medical department or squadron for guidance
- Commander will determine Line of Duty and/or Notice of Eligibility status, if required
- Submit VAERS for any suspected adverse event

888-647-6676

www.tricare.mil/tma/MMSO

Resources

- **MILVAX Agency**
  - www.vaccines.mil
  - www.anthrax.mil
  - www.vaccines.mil/anthrax
  - vaccines@amedd.army.mil
  - 877.GET.VACC
- **DoD Vaccine Clinical Call Center**
  - 866.210.6469
- **Vaccine Healthcare Centers** *for help with adverse event management*
  - www.vhcinfo.org
  - 202.782.0411
- **Information for Civilian Healthcare Providers**

  Call the Military Treatment Facility (MTF) where the member is enrolled OR contact the Military Medical Support Office (MMSO)
  - www.tricare.mil/tma/MMSO
  - 888.647.6676 *if the member is not enrolled to an MTF*
- **USAMMA DOC**
  - www.usamma.army.mil
  - 301.619.4318

Closing

www.vaccines.mil